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10/598,613

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EXAMINER

PAGAN, JENINE MARIE

ART UNIT

PAPER NUMBER

3728

NOTIFICATION DATE

DELIVERY MODE

12/10/2009

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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| | | | |
|------------------------------|--------------------------------------|--------------------------------------|--|
| Office Action Summary | Application No. 10/598,613 | Applicant(s) PEUKER ET AL. | |
| | Examiner JENINE M. PAGAN | Art Unit 3728 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 August 2009 and 30 January 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-25 is/are pending in the application.
- 4a) Of the above claim(s) 11-19 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-10 and 20-25 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 11-19 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 06 September 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date <u>4/5/2007</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. This Office Action acknowledges the applicant's amendment filed on 8/13/2009. Claims 1-25 are pending in the application. Claims 11-19 are withdrawn from consideration. Claim 26 is cancelled. In the listing of claims, claim 26 is listed as currently amended but in the Remarks section of the amendment filed on 1/30/2009, claim 26 is cancelled. For examination purposes, the Examiner will consider claim 26 cancelled.

The text of those sections of Title 35, U.S. code not included in this action can be found in a prior Office Action.

Claim Rejections - 35 USC § 112

2. In light of the Applicant's amendment, the 112 rejection to claim 26 is withdrawn due to cancellation.

Claim Rejections - 35 USC § 103

3. Claims 1-5, 20-22 and 24-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over B. Schwartz (US 3,464,412) in view of M.J. Cohen (US 2,754,590).

Claims 1 and 25: Schwartz discloses:

a capsule body member 20 providing a main chamber 49, and comprising a dispensing opening 42, and wherein the inner wall of the capsule body member comprises a recessed area 24

an applicator member 30 being slideably accommodated in said capsule body member 20, said applicator member 30 providing an auxiliary chamber 45, and wherein said applicator member 30 comprises a through-hole 34 extending from

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the auxiliary chamber 45 to the outer circumferential surface of the applicator member 30

an activator member 35 being slideably accommodated in said applicator member 30

through-hole 34 and said recessed area 24 forming a channel between said main chamber 49 and said auxiliary chamber 45 upon activation of said capsule by said activator member 35

said main chamber 49 and said auxiliary chamber 45 being selectively connectable for fluid communication between said chambers upon activation of said capsule by said activator member 35

Schwartz does not disclose:

movement of said activator member towards said dispensing opening causes movement of said applicator member so that said channel between said main chamber and said auxiliary chamber is formed

However Cohen discloses:

movement of said activator member 26 towards said dispensing opening 22 causes movement of said applicator member 26 so that said channel between said main chamber 18 and said auxiliary chamber 17 is formed

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have the movement of the activator member towards the dispensing opening to form the channel between the main and auxiliary chambers as taught by Cohen instead of the have the movement of the activator

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member away from the dispensing opening to form the channel between the main and auxiliary chambers, since it has been held that a mere reversal of the essential working parts of a device involves only routine skill in the art. In re Einstein, 8 USPQ 167.

Claim 2: Schwartz discloses (Fig 1):

radially extending through-hole 34 in said applicator member 30 is initially covered by the wall of said capsule body member 20

Claim 3: Schwartz discloses (Fig 1):

radially extending through-hole 34 is located in close proximity to the separation wall 33 of said applicator member 30 separating said auxiliary chamber 45 from said mixing chamber 49

Claim 4: Schwartz discloses (Fig 1):

through-hole 34 extends essentially perpendicularly to the longitudinal axis of said applicator member 30

Claim 5: Schwartz discloses (Fig 1):

through-hole extends essentially at an angle smaller than 90° to the longitudinal axis of said applicator member 30

Claim 20: Schwartz discloses (Fig 1):

a dispensing cannula 21 connected to said dispensing opening

Claim 21: Schwartz discloses (Fig 1):

the dispensing cannula 21 is integrally formed with said capsule body member 20

Claim 22: Schwartz discloses (Fig 3):

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cannula 44 is rotatably connected to said capsule body member thus providing a valve

According to the Merriam-Webster Online Dictionary the definition of a needle as disclosed in Schwartz Fig 3, is “a slender pointed rod controlling a fine inlet or outlet (as in a valve)”.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have the cannula rotatably connected to the capsule body as seen in figure 3 instead of integral as in figure 1, since it has been held that constructing a formerly integral structure in various elements involves only routine skill in the art. *Nerwin v. Erlicnman*, 168 USPQ 177, 179.

Claim 24: Schwartz discloses (Col 4:48-59):

main chamber 49 contains a first, preferably powdery, component of said material, and said auxiliary chamber contains a second, preferably liquid, component of said material

4. Claims 6-10 and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over B. Schwartz (US 3,464,412) and M.J. Cohen (US 2,754,590) and further in view of Dragon et al. (US 5,172,807).

Claim 6: Schwartz/Cohen discloses the claimed invention as disclosed in claim 1 and 3 except:

separation wall comprise a raised area extending towards said activator member

However, Dragan discloses (Fig 8):

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separation wall 138 comprise a raised area (see figure above) extending towards said activator member 266

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have a raised area included in the separation wall as taught by Dragan, since *Dragan* shows in Fig 8 that such a modification would allow the two substances an area to begin to mix together.

Claim 7: Schwartz/Cohen discloses the claimed invention as disclosed in claim 1 and 3 except:

raised area comprises an annular bulge

However, Dragan discloses (Fig 8):

raised area (see figure above) comprises an annular bulge

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have the raised area included in annular bulge as taught by Dragan, since *Dragan* shows in Fig 8 that such a modification would allow the two substances an area to begin to mix together in a curvature manner.

Claim 8: Schwartz/Cohen discloses the claimed invention as disclosed in claim 1 and 3 except:

applicator member comprises a sealing element sealing said through-hole of said applicator member against said recessed area of said body member and against the exterior of said capsule

However, Dragan discloses (Fig 8):

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applicator member 266 comprises a sealing element 234 sealing said through-hole of said applicator member 266 against said recessed area of said body member and against the exterior of said capsule

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have the applicator member include a sealing element as taught by Dragan, since *Dragan* states at column 5 lines 35-37 that such a modification would keep the substances separate until ready to combine and use on the patient such as powder and water to mix for cement to fix a filling.

Claim 9: Schwartz/Cohen discloses the claimed invention as disclosed in claim 1 and 3 except:

activator member comprising an activator sealing element for sealing said activator member against said applicator member

However, Dragan discloses (Fig 8):

activator member 224 comprising an activator sealing element 268 for sealing said activator member 224 against said applicator member 266

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have the activator member include a sealing element as taught by Dragan, since *Dragan* states at column 5 lines 47-52 that such a modification would keep the substances separate until ready to combine and use on the patient such as powder and water to mix for cement to fix a filling.

Claim 10: Schwartz/Cohen discloses the claimed invention as disclosed in claim 1 and 3 except:

sealing elements are manufactured by a two-component injection molding process together with the capsule body member, the applicator member and said activator member

However, Dragan discloses (Fig 8):

sealing elements 234/268 are manufactured by a two-component injection molding process together with the capsule body member, the applicator member 266 and said activator member

In accordance to MPEP 2113, the method of forming the device is not germane to the issue of patentability of the device itself. Therefore, this limitation has not been given patentable weight. Please note that even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product, i.e. sealing elements, does not depend on its method of production, i.e. two-component injection molding process. In re Thorpe, 227 USPQ 964, 966 (Federal Circuit 1985).

Claim 23: Schwartz/Cohen discloses the claimed invention as disclosed in claim 1 but it does not specifically disclose:

dental materials are glass ionomer cements or resin modified glass ionomer cements

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have dental materials be made of glass ionomer cements or resin modified glass ionomer cements, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its

suitability for the intended use as a matter of obvious design choice. In re Leshin, 125 USPQ 416.

Response to Arguments

5. In response to the Applicant's request to reconsider the foreign references that were not considered in the previous Office Action, in light of the Applicant's submission of copies of the foreign references, they have now been considered.

6. In response to the Applicant's remarks regarding the 112 and 101 rejections to claim 26, in light of the Applicant's amendment, the 112 rejection to claim 26 is withdrawn due to cancellation.

7. Applicant's arguments filed 8/13/2009 and 1/30/2009 have been fully considered but they are not persuasive. In response to the Applicant's argument that the references of Schwartz does not disclose movement of said activator member towards said dispensing opening causes movement of said applicator member so that said channel between said main chamber and said auxiliary chamber is formed, all of the structures that are claimed by the Applicant are disclosed in Schwartz it is obvious that having the structures claimed can perform different functions intended by the user. As stated above, a mere reversal of the essential working parts of a device involves only routine skill in the art.

Conclusion

8. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JENINE M. PAGAN whose telephone number is (571)270-3216. The examiner can normally be reached on Monday - Thursday, 8am-4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mickey Yu can be reached on (571) 272-4562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Mickey Yu/
Supervisory Patent Examiner, Art Unit 3728

/Jenine M Pagan/
Examiner, Art Unit 3728